

SUMMARY OF COMMENTS RECEIVED ON PRIORITIZATION PROCEDURE

Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
May 1997

In a public notice published in the California Regulatory Notice Register on October 4, 1996, the Office of Environmental Health Hazard Assessment (OEHHA) requested comment on the refined prioritization procedure. The notice initiated a 60-day comment period which ended on December 4, 1996. The procedure describes how OEHHA will identify, prioritize, and select candidate chemicals for consideration by the Science Advisory Board Identification Committees. During the comment period, OEHHA held a public workshop on November 15, 1996 to discuss and receive comments on the refined prioritization procedure. Numerous comments were received. Because the request for comments was not part of a formal regulatory action, responses to each comment received are not required. OEHHA has summarized the comments by general topic area and will respond to the comments collectively by topic area. (Not all comments received were directly germane to the prioritization procedure.) Although we do not formally respond to each comment, OEHHA did give careful consideration to each comment in determining our final actions relating to the prioritization procedure. The final prioritization procedure incorporates OEHHA's responses to the comments received.

Oral and/or written comments were received from:

Natural Resources Defense Council
Cosmetic, Toiletry and Fragrance Association
Nonprescription Drug Manufacturers Association
Murray and Associates
Environmental Defense Fund
Gibson, Dunn and Crutcher
Grocery Manufacturers of America
Dr. Joseph Landolph
Chemical Industry Council of California
Environmental Working Group
Technology Sciences Group
California Grape and Tree Fruit League

Examples of the comments received are summarized below under general topic areas, followed by OEHHA's action.

MATERNAL AND SYSTEMIC TOXICITY

Comments were received that support the concept that maternal toxicity and systemic toxicity be considered in assigning the level of concern.

Support the concept that developmental toxicants should not receive a high ranking if they cause effects secondary to maternal toxicity.

Support recommendation that maternal and systemic toxicity are legitimate reasons to assign lower levels of hazard concern for developmental and reproductive toxicants.

Action:

No opposition was received; therefore, this refinement was incorporated into the prioritization procedure.

OTHER RELEVANT DATA

Comments were received that support the use of “other relevant data”.

Agree that the nature and severity of effects should be taken into account in assigning levels of hazard concern.

Support the use of epidemiological, animal and other relevant data.

Concur with the use of positive and negative studies in assessing the overall level of concern.

Strongly support the use of other relevant data, including “information on mechanism of action, chemical structure, metabolism, and genotoxic activity.

Action:

No opposition was received; therefore, this refinement was incorporated into the prioritization procedure.

FOCUS ON CHEMICALS WITH HIGH HAZARD CONCERNS

Comments were received that support the concept of focusing first on chemicals with a high hazard concern.

Support the preparation of HIDs only on those chemicals ranked with high level of hazard concern.

Support the concept of initially focusing on chemicals with a high hazard concern.

Focusing first on those chemicals of high toxicity concern is a necessary element of conforming the prioritization process to the clearly shown standard.

Agree with weight of evidence approach.

Support the commitment to use rational methods and sound science in selecting chemicals. The change calling for OEHHA to establish the priority rankings is acceptable.

Comments were received that oppose the concept that exposure should not play a key role in assigning priority status.

Proposed criteria (use only hazard concern to establish priorities) are scientifically insupportable. Human exposure potential ruled out in setting priorities for listing. Makes no public health sense to address as high chemicals that are without substantial use or exposure in California.

Suggest that chemicals that have little or no exposure potential remain in Category I.

Process should maximize the effectiveness of Proposition 65 by examining the practical effect of a possible listing on public health. Examples: High priority should not be given to chemicals when a Proposition 65 warning would conflict with valid public health messages, or when exposures of concern are exempt from Proposition 65, or where actual exposures pose little or no risk.

Suggest that if potential human exposure data is available that it be considered in moving the chemical more rapidly through prioritization to be brought before the appropriate Committee.

Comments were also received that support the concept that exposure should not play a key role in assigning priority status.

Believe that exposure evidence should be secondary to toxicity evidence. May be logical to distinguish among chemicals of equal toxicological concern, but not to accelerate consideration of less toxic chemicals.

Disagree that exposure should play a greater role in prioritization. Proposition 65 is focused on toxicity, it only authorizes the listing of chemicals clearly shown to cause cancer or reproductive toxicity. Exposure data not regularly available.

Action:

Concern was raised that limiting the use of exposure data in determining the chemicals for placement on the Candidate List for consideration by the Committee could delay consideration of chemicals with high potential exposure, but lesser degrees of hazard concern. These concerns will be addressed to some extent by incorporating exposure information once chemicals are placed on the Candidate List and it becomes necessary to determine in what order chemicals are drawn from the Candidate List for preparation of hazard identification documents. Chemicals will be selected from the Candidate List based on their exposure level of concern. Chemicals with both the highest level of hazard concern and the highest level of exposure concern will be selected first from the Candidate List to be brought forward before their respective Committee. Chemicals on the Candidate List (those with “high hazard concern”) for which there are lower exposure concerns in California will, in general, be addressed subsequent to those determined to have both a “high hazard concern” and a “high level of exposure concern.” Thus, the end result is a form of triage, in which chemicals with the highest level of hazard concern and the highest level of exposure concern are selected first and brought forward expeditiously for Committee consideration. On balance, OEHHA believes that focusing first on chemicals with high hazard concern is consistent with the focus of the Proposition and will allow for expedited progress on those chemicals with the strongest evidence of potential to cause cancer, birth defects, or other reproductive harm.

CRITERIA FOR HIGH HAZARD CONCERN

Comments were received that suggest a change in the criteria for assigning the level of hazard concern.

Current proposal states “Chemicals will be assigned a high level of hazard concern if this preliminary evaluation indicates the existence of evidence that is likely to

demonstrate a strong potential to cause cancer or developmental/reproductive toxicity.” Recommend adding “clearly shown” to this sentence, to read, “A chemical will be assigned a high level of hazard concern if this preliminary evaluation indicates a strong likelihood that the weight of evidence will support a finding that the chemical has been clearly shown to cause cancer or reproductive toxicity.”

Action:

It was suggested that the criteria for assigning a high level of hazard concern be changed to include the “clearly shown” standard. This was rejected on the basis that only the Committees can conclude that a chemical has been “clearly shown” to cause cancer or reproductive toxicity. Further, it would suggest that OEHHHA had prejudged the scientific evidence during the assignment of the prioritization of chemicals.

CATEGORY II TERMINOLOGY

Comments were received that stated “qualified” support for the change in terminology of list of chemicals. Comments also argued for the elimination of the specific hazard rankings within Category II.

Urge that Category II chemicals not be characterized (as medium-high, medium, or low).

Stigma remains as long as Category II chemicals are characterized. Compels industry to present OEHHHA with additional data to lower its chemical ranking.

Proposed alternative is to rename Candidate List as chemicals for which “a basis exists for preparing hazard identification documents”; and divide Category II into 2 subcategories, 1) “no basis exists at this time for preparing hazard identification documents” (medium-high), and 2) “no basis exists for preparing hazard identification documents” (medium and low).

Should be able to move a chemical from the Candidate List to Category II if more detailed analysis reveals that the chemical should not have a high priority.

Agree with elimination of term “priority list” for “candidate list”.

Recommend that essential trace elements on the Donald et. al. list remain in Category I. Elements should not receive any priority.

Action:

Placement into Category II is based on the review of the available scientific evidence and on the conclusion that the chemical does not warrant elevated consideration at this time.

While support was received on the change in terminology from priority list to candidate list, concerns of stigmatization remained as long as the Category II chemicals were assigned hazard levels of concern. There is a need, however, to retain the “characterization” (medium-high, medium, low, no identified concern, and inadequate data) of the chemicals. The purpose is primarily to document the staff work invested in evaluating the chemical and to track OEHHHA’s opinion concerning the scientific evidence available and reviewed at the time the designation was made. This will avoid starting out at the beginning when the Category II chemicals come under consideration for further prioritization.

RANDOM SELECTION

Comments were received that oppose the use of random selection for determining the chemicals to be evaluated.

Random selection is inconsistent with prioritization.
Available data should be used. Random selection should be used only for chemicals for which nothing is known.

“Unbiased random selection” is an oxymoron.

Comments were also received that support the use of random selection for determining the chemicals to be evaluated.

Support random selection of candidates, like a table of random numbers.

Agree with random, unbiased selection of chemicals from Category I. Suggest use of random numbers table.

Action:

No matter what criteria for evaluation are used, some mechanism is needed to determine which chemicals are evaluated first. OEHHHA will use random selection only at the very first step in the process, to determine which chemicals are selected from Category I for evaluation and the development of draft data summaries and draft priorities. OEHHHA will

use the random selection process as a pilot program for eighteen months, after which OEHHA will evaluate its experience under the process and make changes as warranted.

Opposing commenters believed that available toxicological information should be considered in some fashion in prioritizing chemicals for evaluation, suggesting that “unbiased selection” should not weigh heavily if the goal of the procedure is to bring forward those chemicals which are of the greatest hazard concern. OEHHA’s ongoing goal for prioritization has been to use an approach that is consistent, predictable and open to public input, that focuses Committee resources on issues that most merit their consideration, and is free from selection bias.

A remaining issue is to determine how best to achieve “random” selection. Comments supporting random selection suggested that a random number table be used.

SUPPLEMENTAL ANALYSIS

Comments were received that oppose the supplemental analysis step.

Redundant forums for debate should not be created.
Proposal allows too many opportunities for comment on issues of science.

Proposal expands the number of procedural steps chemical proponents can exploit to delay evaluation. Allows 2 supplemental analyses steps.

Do not support proposal because too much time and energy spent before chemicals are sent to review by the State’s qualified experts.

“Refinements” appear to be designed to forestall evaluation of specific chemicals.

OEHHA is “usurping the role of qualified expert” by controlling the process to an excessive degree. OEHHA will refrain from bringing chemicals before the Committees until virtually all scientific uncertainty has been resolved.

Comments were also received that support the supplemental analysis step.

Tiered evaluation process makes good sense. Certain circumstances will warrant supplemental analyses, many will not.

Supplemental analysis when scientifically indicated seems appropriate.

Strongly advocates adoption of supplemental analysis approach.

If mechanistic data exists on a chemical, it should be looked at as part of the supplemental analysis.

Action:

The opposition received concerning supplemental analysis appears to stem from a misperception of the circumstances under which an analysis will occur. The description of the process has been modified to clearly state that although a supplemental analysis may address several issues, a chemical will undergo, at most, only one supplemental analysis. This affirmative statement should alleviate the concerns that too many opportunities exists for public intervention in the procedure. The supplemental analysis step will be incorporated into the prioritization procedure and performed as warranted. This will allow a “tiered” evaluation, which makes the best use of limited resources.

POSTPONEMENT

Comments were received that support postponement of further consideration by OEHHHA if a chemical is under consideration by an authoritative body.

Support postponement of consideration of chemicals under evaluation by an authoritative body within a reasonable timeframe (1-3 years).

Support recommendation to postpone consideration for chemicals under evaluation by an authoritative body.

Action:

No opposition was received; therefore, the refinement was incorporated into the prioritization procedure.

EXPAND POSTPONEMENT CRITERIA

Comments were received that recommend expanding the postponement criteria.

Appropriate to postpone consideration of a chemical when a decision could significantly benefit from an important new study in progress whether or not the study is being conducted by an authoritative body.

Recommend postponement be expanded to include chemicals under scientific study by other legitimate organizations.

Action:

Postponement of prioritization when a chemical is under consideration by an authoritative body is reasonable because there is a statutory provision which would allow for the administrative listing of the chemical if the authoritative body formally identifies a chemical as causing cancer or reproductive toxicity. The postponement is reflective of the possibility that the chemical may be a candidate for administrative listing, thereby foregoing the need to have the State's qualified experts render an opinion.

In addition, OEHHHA recognizes that on occasion it may be reasonable to postpone prioritization, for a defined period of time, to allow for the completion of a study undertaken by, on behalf of, or for use by an authoritative body. OEHHHA may, at its discretion, choose to postpone prioritization when the study results would allow OEHHHA to prioritize a chemical for endpoints for which there otherwise would be insufficient data, or when OEHHHA determines that the study is of sufficient significance so as to be relevant to the assignment of a priority to the chemical. Prioritization of postponed chemicals would proceed when the study results become available. Postponement will be noted in the tracking database.